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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,447	11/13/2003	Gattadahalli M. Anantharamiah	21085.0143U2	8707

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EXAMINER	
KOLKER, DANIEL E	
ART UNIT	**PAPER NUMBER**
1649	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/712,447	ANANTHARAMIAH ET AL.	
	Examiner	Art Unit	
	Daniel Kolker	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/29/06*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 9-34* is/are pending in the application.

4a) Of the above claim(s) *9-13 and 18-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6 and 14-17* is/are rejected.

7)☒ Claim(s) *4 and 5* is/are objected to.

8)☒ Claim(s) *1-6,9-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The remarks and amendments filed 29 November 2006 have been entered. Claims 7 – 8 have been canceled. Claims 1 – 6 and 9 – 34 are pending.

Election/Restrictions

2. Claims 9 – 13 and 18 – 34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 16 March 2006.

3. This application contains claims 9 – 13 and 18 – 34 drawn to an invention nonelected with traverse in the reply filed on 16 March 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

4. Claims 1 – 6 and 14 – 17 are under examination.

Withdrawn Rejections and Objections

5. The following objections and rejections set forth in the previous office action are withdrawn:

A. The objections to the claims are withdrawn in light of the amendments, which addressed all of the examiner's concerns with respect to formalities.

B. The rejection of claims 1 – 6 and 14 – 17 under 35 USC § 112, first paragraph, for lack of adequate written description is withdrawn. The examiner concedes that while the claims are broad, the invention encompassed therein is sufficiently described.

C. The rejections under 35 USC § 112, second paragraph are withdrawn in light of the amendments which clarify the scope of patent protection desired.

D. The rejection under 35 USC § 102(b) is withdrawn in light of the arguments. Applicant is correct that the limitations of independent claim 1 are necessarily incorporated into the dependent claims, and that the prior art sequence cited by the examiner does not have the appropriate residues at each position of the generic sequence SEQ ID NO:210, recited in claim 1. Thus applicant is correct that the prior art fails to teach every limitation of the invention recited in the claims.

Maintained Rejections and Objections

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 – 4, 6, and 14 – 17 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for proteins comprising SEQ ID NO:5 as recited in claim 5, does not reasonably provide enablement for the full breadth of proteins comprising the amino acid sequence of SEQ ID NO:210 or for proteins compris/"a sequence of consecutive amino acids of SEQ ID NO:5" as recited in claim 4. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection is maintained for the reasons of record. Briefly, claim 1 encompasses a very large number of possible protein sequences that the specification does not disclose how to use. The protein of SEQ ID NO:5 is within the scope of the claim and is asserted to be useful in binding of LDL or VLDL to cells. However, the full scope of claim 1 is much broader than what is disclosed. Claim 1 allows for positions 1, 7, and 8 to be any of four amino acids and positions 2, 5, 6, 9, 10, 12, and 13 to be any hydrophobic amino acid. There is no requirement that the protein have any particular function. Claim 1 does not require that the protein decrease cholestrol, or bind LDL, or modulate LDL binding to a cell. While claims 14 and 15 do recite certain functional limitations related to LDL and VLDL, these limitations are not present in claim 1. As independent claim 1 is necessarily broader than any dependent claim, it incorporates subject matter beyond the scope of what is in the dependent claims. Put another way, claim 1 encompasses proteins that do not enhance binding or degradation of LDL and VLDL.

The specification does not teach the artisan how to use the full genus of proteins encompassed by claim 1 which form amphipathic alpha helices. Applicant argues, on p. 10 of the remarks, that proteins which do not modulate LDL or VLDL are useful because they can be used to generate antibodies. However, the antibodies generated would not be expected to purify proteins which actually do modulate LDL or VLDL, they would instead be expected to purify the antigens against which they are raised. Thus the antibodies raised against proteins which do not modulate LDL or VLDL would be expected to be useless. Since the claimed sequence (i.e. SEQ ID NO:210, recited in claim 1) is so short, even changing one or two

residues would result in changing a large degree of the structure of the protein. Random protein mutations would be expected to result in inactive proteins. See for example Geysen et al. (1988. Journal of Molecular Recognition 1:32-41), who teach that changing amino acid sequences alters the ability of a protein to be recognized by an antibody, and changes the ability of a protein to elicit an antibody upon administration to an animal. Thus the skilled artisan would not know how to use proteins that do not modulate LDL or VLDL. The specification does not teach the artisan how to use the inactive proteins. Therefore claim 1, from which all other claims ultimately depend, is not enabled over its full scope, as it encompasses an unreasonably large number of proteins which would be expected to be inactive, and antibodies raised against proteins which do not modulate LDL or VLDL would not be expected to recognize protein that in fact modulate LDL or VLDL. As such, the proteins which do not modulate LDL or VLDL could only be used to make antibodies that purify products which the specification does not disclose how to use. Thus the examiner maintains his opinion that proteins which do not in fact modulate LDL or VLDL are not enabled by the specification, because it does not teach the artisan how to use them.

Furthermore, it is noted that limiting the claims to proteins which form amphipathic alpha helices does not limit them to those proteins which the specification teaches the artisan how to use. The art recognizes that "amphipathic alpha helix" is a structural motif involved in a wide range of divergent cellular and physiological functions. See for example Bechinger (2000. Current Opinion in Chemical Biology 4:639 – 644), who teaches that proteins comprising such helices are often found in membrane-spanning regions of proteins and can also be found in certain antibiotics as well as channels (see p. 640, second column). Kandel (1991. Principles of Neural Science, 3rd edition, pp. 188 – 189) teaches that such helices are also found in transcription factors. The specification does not disclose to the artisan which amphipathic helices are useful, either in the context of serum cholesterol levels or as antibiotics, membrane spanning proteins, or transcription factors. Thus the claims currently encompass a huge number of possible protein sequences for which enablement has neither been demonstrated nor could it be accurately predicted.

Finally, claim 4 recites "wherein the polypeptide comprises a sequence of consecutive amino acids of SEQ ID NO:5". This is considerably broader than the recitation "the sequence of consecutive amino acids" The specification does not provide the artisan with adequate guidance as to which amino acids of SEQ ID NO:5 must be present. The claims do not require that any particular function be present in "a sequence of consecutive amino acids of SEQ ID NO:5", even

given the fact that the limitation of structure (amphipathic helix) is imported from claim 1. Thus the skilled artisan could not determine which residues of SEQ ID NO:5 must be preserved in the products of claim 4. It is clear that claim 4 is of broader scope than claim 5, which recites "wherein the polypeptide comprises the sequence Gly-Ile-Arg-Arg-Phe-Leu-Gly-Ser-Ile-Trp-Arg-Phe-Ile-Arg-Ala-Phe-Tyr-Gly (SEQ ID NO:5)". In claim 5, all residues of SEQ ID NO:5 must be present whereas in claim 4 only a sequence of consecutive residues must be present. As the specification does not provide guidance as to which residues are to be retained, the artisan would have to resort to undue experimentation in order to determine this.

Conclusion

7. No claim is allowed.

8. Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. Applicant is advised that search of the following sequences has revealed that they are all free of the prior art: SEQ ID NO:2, 5, 8,10, 13, 115 – 117, 210.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Daniel E. Kolker, Ph.D.
February 22, 2007

ROBERT C. HAYES, PH.D.
PRIMARY EXAMINER